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(54) **Test member for assessing a component in a bodily fluid**

Testvorrichtung zur Bestimmung von einer in einer körperlichen Flüssigkeit enthaltenen Verbindung

Dispositif de test pour détecter un composant dans un fluide corporel

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by a closed air gap which provides a circumferential flow barrier so that the sample is retained within the disc or pad. As a result, more consistent results can be achieved and the amount of sample required can be consistently less than that required when a conventional test strip is used or when the hitherto proposed back read techniques are used.

SUMMARY OF THE INVENTION:

Accordingly, the present invention provides a test member for assessing a component in a fluid to be tested, characterised in that the test member comprises a support member carrying a membrane impregnated with or carrying one or more reagents required for the test, which membrane is surrounded at least circumferentially by a flow barrier which inhibits flow of the sample fluid through the lateral edges of the membrane, the flow barrier being provided by a closed air gap around the circumferential periphery of the membrane which is sufficient to break the capillary flow from the edge of the membrane.

Preferably, the membrane is made from a micro-porous material which is impregnated with a gel matrix containing a mixture of one or more enzyme reagents with one or more chromogen materials, which mixture is adapted to interact with at least one of the non-cellular component of a fluid sample applied to one face of the membrane so as to develop a colour in the visible spectrum which can be observed from the opposed face of the membrane. Preferably, the gel matrix blinds a substantial length of at least a major proportion of the pores in the membrane so that rupture of cell walls in cellular components of the material to be tested is reduced.

Preferably, the support member is a white or opaque plastics strip having an aperture therethrough in register with the membrane.

The support member and the membrane can take any suitable form, depending upon the scanning technique which is to be used. Thus, the invention can be applied to a conventional axially elongated blood test stick in which the support member is the stick. Such a stick is usually formed from an opaque white plastic carrying the membrane at or adjacent one end thereof. In this case, the sample is applied to the exposed upper face of the membrane and the colour which develops in the membrane is observed after a specified time from the exposed upper face of the membrane and the back read technique is not used. The invention, in this case, reduces lateral spread of the colour away from a small area of the reagent mixture in the membrane and thus enables a smaller sample to be used than has been hitherto required in a conventional front read test strip.

However, the invention is of especial benefit in test methods using the back read test method. It is therefore preferred that the support member either be translucent so that the colour developed in the membrane can be observed through the strip; or that the strip be formed with an aperture therethrough in register with the membrane so that the colour can be observed directly through that aperture. Again the plan shape of the membrane and support member can be of any suitable shape or form to operate in the scanning device for which the test member is intended, for example square, rectangular, polygonal or, preferably, circular.

The membrane is preferably sized so that it becomes saturated with the fluid sample applied to it so that the fluid is substantially uniformly distributed throughout the membrane.

The support member is typically self supporting and acts as the sole support for the membrane. However, it is within the scope of the invention to apply the membrane to an intermediate support which is then held in a rigid member. For example, the membrane can be provided by a thin micro-porous membrane which is held by a suitable ring clamp or other means to form the end face of an open ended chamber in a metal or plastic capsule or other receptacle into which a sample of blood is introduced so that the sample contacts the internal face of the membrane.

For convenience, the invention will be described hereinafter in terms of a disc or pad of micro-porous membrane which is secured to one face of a disc or rectangle of a polyvinyl or other sheet plastic as the self supporting support member.

The support member, the membrane for the disc or pad and the reagent mixture applied to or impregnated into the membrane may be selected from a wide range according to the type of test which is to be carried out. As stated above, the back read technique is of especial application in testing the non-cellular component of a bodily or other fluid which contains one or more cellular components which are separated from the fluid under test by the micro-porous nature of the membrane. The invention can thus be used in monitoring plant fluids as well as bodily or other fluids.

For convenience, the invention will be described hereinafter in terms of testing for glucose in a blood sample.

The membrane will typically have a mixture of a gel matrix, one or more enzymes and one or more chromogens applied as a coating to one face thereof. Preferably, the membrane is impregnated with the mixture so that the mixture is substantially uniformly distributed throughout the membrane and preferably blinds substantially all of the pores in the membrane for at least 50%, preferably at least 75%, of their length. The nature of the mixture and the amount loaded onto the membrane can readily be selected using criteria known in the art.

The membrane is surrounded by a flow barrier. Where the flow barrier is provided by a barrier coating or collar which surrounds the periphery of the membrane, gaps or cracks may be formed between the barrier coating or member and the support member so that capillary flow takes place from the edge of the mem-

through the aperture 3 in the support 2 to give an indication of the glucose level in the blood sample. Due to the air gap 5, the blood plasma cannot all bleed radially outward from the membrane, so that the colouration is retained in the area of the membrane to be observed. By sizing the membrane so that the area observed corresponds substantially to the area underlying the central aperture 11 in ring 4 and by sizing ring 4 so that it overlies only the peripheral edge of the membrane disc 1, the loss of colouration by diffusion to the peripheral area of the membrane is reduced and the effect of that diffusion is minimised. As a result, only a small sample of blood need be used and substantially consistent results can be achieved with that small size of sample.

By way of comparison, when steps are taken to avoid the formation of air gap 5, the colouration migrates beyond the edge of the membrane disc and the colouration observed through aperture 3 varies with time and with the precise portion of the disc which is observed.

Claims

1. A test member for assessing a component in a fluid to be tested, characterised in that the test member comprises a support member (2) carrying a membrane (1) impregnated with or carrying one or more reagents required for the test, which membrane (1) is surrounded at least circumferentially by a flow barrier (5) which inhibits flow of the sample fluid through the lateral edges of the membrane (1), the flow barrier (5) being provided by a closed air gap (5) around the circumferential periphery of the membrane (1) which is sufficient to break the capillary flow from the edge of the membrane (1).

2. A test member as claimed in claim 1, characterised in that the membrane (1) is made from a micro-porous material which is impregnated with a gel matrix containing a mixture of one or more enzyme reagents with one or more chromogen materials, which mixture is adapted to interact with one or more non-cellular components of a fluid sample (10) applied to one face of the membrane (1) so as to develop a colour in the visible spectrum which can be observed from the opposed face of the membrane (1).

3. A test member as claimed in either of claims 1 or 2, characterised in that the reagent mixture is in the form of a gel matrix which blinds a substantial length of at least a major proportion of the pores in the membrane (1) so that rupture of cell walls in cellular components of the material (10) to be tested is reduced.

4. A test member as claimed in any one of the preceding claims, characterised in that the support member (2) is an axially elongated member carrying the membrane (1) adjacent one end of the elongated member.

5. A test member as claimed in any one of the preceding claims, characterised in that the support member (2) is either translucent and/or has an aperture therethrough in register with the membrane (1) so that the colour developed in the membrane (1) can be observed through the support member (2).

6. A test member as claimed in any one of the preceding claims, characterised in that the membrane (1) is in the form of a disc which forms the end face of an open ended chamber (11) in a sample receiving member (4) into which a sample of the fluid (10) to be tested is to be introduced so as to contact one face of the membrane (1).

7. A test member comprising a reagent-carrying membrane (1) supported on a support member (2), to which membrane (1) a fluid sample (10) is to be applied to generate a coloured component by interaction with the reagent, which colour is to be observed over a given area of the membrane, characterised in that the circumferential periphery of the membrane is surrounded by a closed air gap (5) sufficient to prevent capillary flow of the coloured component radially outward from the edge of the membrane (1).

8. A method for testing a fluid (10) which comprises applying it to a membrane (1) of a test member as claimed in any one of the preceding claims.

9. A method as claimed in claim 8, characterised in that the fluid (10) is blood which is applied to one face of the membrane (1), the membrane (1) carries or is impregnated with a reagent mixture which develops a colour upon reaction with one or more components of the blood, and the colour is observed at the opposite face of the membrane to that to which the sample is applied.

Patentansprüche

1. Testvorrichtung zur Bestimmung einer Komponente in einem zu testenden Fluid,
dadurch **gekennzeichnet,**
daß die Testvorrichtung einen Träger (2) aufweist, der eine Membran (1) trägt, die mit einem für den Test erforderlichen Reagenz oder mit mehreren Reagenzien getränkt ist oder diese trägt, daß die Membran (1) zumindest am Umfang durch eine Flußbarriere (5) umgeben ist, welche den Fluß des Probenfluids durch die seitlichen Ränder der Membran (1) verhindert und daß die Flußbarriere (5) durch einen zur Unterbrechung des Kapellarflusses

est sous la forme d'une matrice de gel qui obstrue une longueur importante d'au moins une proportion majeure des pores dans la membrane (1) de façon à ce que la rupture des parois de cellules dans les composants cellulaires de la matière (10) devant être analysée soit réduite.

4. Dispositif d'analyse selon l'une quelconque des revendications précédentes, caractérisé par le fait que l'élément support (2) est un élément allongé axialement supportant la membrane (1) adjacente à une extrémité de l'élément allongé.

5. Dispositif d'analyse selon l'une quelconque des revendications précédentes, caractérisé par le fait que l'élément support (2) est ou translucide et/ou présente une ouverture traversante coïncidant avec la membrane (1) de façon à ce que la couleur développée dans la membrane (1) puisse être observée à travers l'élément support (2)

6. Dispositif d'analyse selon l'une quelconque des revendications précédentes, caractérisé par le fait que la membrane (1) est sous la forme d'un disque qui forme la face d'extrémité d'une chambre (11) à extrémité ouverte dans un élément (4) recevant un échantillon dans lequel un échantillon du fluide (10) devant être analysé doit être introduit de façon à être en contact avec une face de la membrane (1).

7. Dispositif d'analyse comprenant une membrane (1) supportant un réactif, supportée par un élément support (2), un échantillon fluide devant être appliqué sur la membrane (1) pour générer un composant coloré par interaction avec le réactif, laquelle couleur devant être observée sur une surface donnée de la membrane, caractérisé par le fait que la circonférence de la membrane est entourée par un espace d'air fermé (5) suffisant pour empêcher l'écoulement capillaire du composant coloré radialement vers l'extérieur à partir du bord de la membrane (1).

8. Procédé d'analyse d'un fluide (10) qui comprend l'application à une membrane (1) d'un dispositif d'analyse tel que revendiqué à l'une quelconque des revendications précédentes.

9. Procédé selon la revendication 8, caractérisé par le fait que le fluide (10) est du sang qui est appliqué sur une face de la membrane (1), la membrane porte ou est imprégnée par un mélange réactif qui développe une couleur lors de la réaction avec un ou plusieurs composants du sang, et la couleur est observée à la face de la membrane opposée à celle sur laquelle est appliqué l'échantillon.

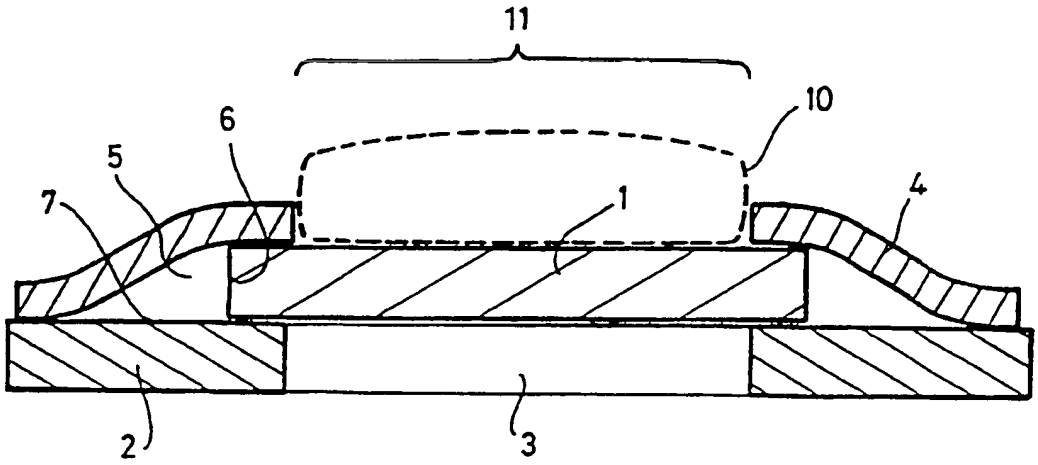

Fig. 1

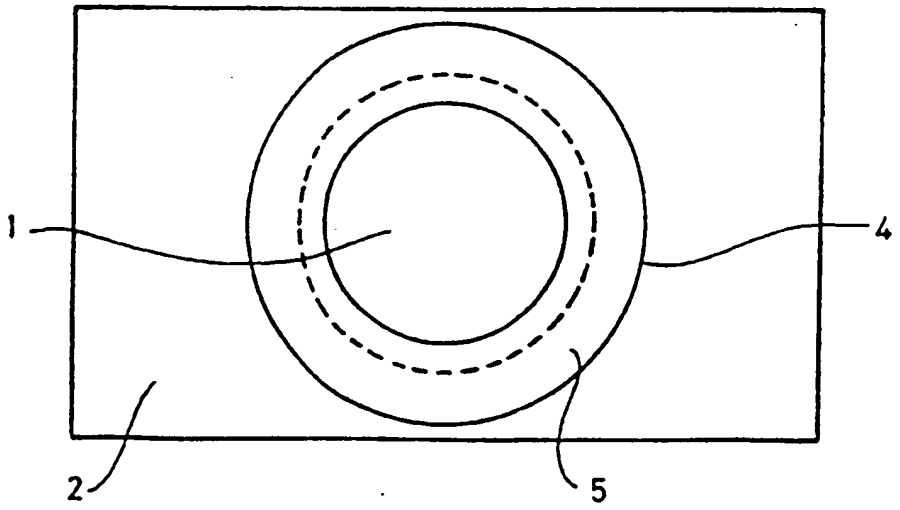

Fig. 2